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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,933	01/30/2001	Rosalynn D. Gill-Garrison	620-130	9089

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NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/771,933

Applicant(s)

GILL-GARRISON ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' arguments, filed 25 May 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-28 are currently pending.

#### **Drawings**

In response to Applicant's request the Examiner has reviewed the drawings submitted 30 January 2001. Applicant is requested to please re-submit the drawings, as there appears to be a line drawn across both drawings 1 and 2. This may be a word processing or scanning error. The Examiner thanks Applicant in advance for his/her cooperation.

#### **Information Disclosure Statement**

In response to Applicant's request to confirm that the list of references in the letter of 24 January 2005 have been considered, the Examiner confirms that these references have been considered and that the line through the references must have occurred as a word processing error or as an error in scanning.

#### **Claim Objections**

Claims 1 and 14 are objected to because of the following informalities: Appropriate correction is required. Claims 1 and 14, step (i) recites "one allele of each genetic locus known

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to be associated”. A verb is missing. Perhaps Applicant intends the claim to read “genetic locus is known to be associated”. Correction is required.

### **Interview Request**

Applicant has requested an interview with the Examiner. It is noted that the Examiner attempted to comply with Applicant’s request in March of 2005 and had scheduled an interview for the 7 March 2005. Applicant subsequently cancelled the interview. The Examiner is willing to conduct an interview upon Applicant’s receipt of the current Office Action. Applicant is invited to telephone the Examiner to set up a time and date that is mutually convenient.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 14 are indefinite at step (iii) for reciting “present in said subject, wherein said alleles are at one or more of the genetic loci of said first dataset of said human subject”. This is unclear. Perhaps Applicant intends that the said alleles correspond to one or more genetic loci. It is unclear whether the alleles are in the loci, or in the data set. Also, “said human subject” is redundant, as “said subject” was already recited. Clarification is requested.

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**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over 5,985,559 (Brown), in view of Perera et al. (Carcinogenesis (2000) Vol. 21, pages 517-524), for the reasons set forth in the previous Office Action.

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*Response to Applicant's Arguments*

1. Applicant argues that “once data from the patient is imputed into the system, the generation of the lifestyle plan requires no further patient input. This is in contrast to Brown, which relates to an iterative process, as illustrated in the attached flowcharts”.

This is not persuasive, as there is no requirement in the instant claims that forbids “no further patient input”. In fact the instant claims do not recite any limitations with regard to patient input.

2. Applicant argues further that “the scripts of Brown cannot be equated to the personalized lifestyle advice plan of the present invention. In particular, the scripts of Brown are elements which require a patient response in order for the system to function”.

This is not persuasive, as there are no limitations in the instant claims, such that further patient information cannot be input. It is noted that the claims recite open claim language and therefore may comprise steps beyond those explicitly recited. The claims do not prohibit a system which is iterative. Brown in view of Perera make obvious the generation of a lifestyle plan, as stated in the previous Office Action.

3. Applicant argues that “Brown does not contemplate the provision of a specific lifestyle advice plan; rather the ‘geno-pheno map’ appears to represent a general resource for physicians or ‘persons involved in gene research’ to investigate disease processes and therapies”.

This is not persuasive, as stated in the previous Office Action. Brown teaches a computer system and method for interpreting a patient’s gene sequence and his or her environment and lifestyle to come up with a personalized prognosis, which is a lifestyle plan.

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4. Applicant argues that “no element of Perera would have motivated the ordinarily skilled person to alter the fundamental teaching of Brown that the provision of a “health monitor” requires iterative patient response. The person of ordinary skill would have needed to associate these genes with appropriate ‘scripts’ for presentation to a subject”.

This is not persuasive as the Examiner set forth a motivation at page 6, lines 12-21. Further, Perera is relied upon to teach various genetic traits, associated with disease, which are associated with disease risk. Brown teaches every other element of the claimed invention. Therefore, the Examiner maintains that Brown, in view of Perera make obvious the claimed invention.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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### Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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August 4, 2005  
Lori A. Clow, Ph.D.  
Art Unit 1631  
*Lori A. Clow*

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
8/4/05